FINDING OF NO SIGNIFICANT IMPACT

for

Dura Se^{R} -120

Schering Animal Health
Food Additive Petition 2210

On January 6, 1988, Schering Animal Health, a division of Schering-Plough Corporation, filed a food additive petition with the Center for Veterinary Medicine (CVM) that would provide for the use of a sustained-release bolus to deliver selenium at 3 mg/head/day in beef and dairy cattle. In the notice of filing of the food additive petition (FAP Number 2210, January 6, 1988, 53 FR 289), CVM requested comment on the environmental assessment (EA) submitted by the petitioner. No comments were received.

CVM reviewed the EA and found deficiencies that were later addressed in a revised EA (dated May 6, 1988) now being made available for comment with this finding of no significant impact (FONSI).

CVM is making these documents available for comment in advance of any decision to approve the new dosage form because the revised EA and this FONSI rely in part on a previous action with selenium that is not yet fully resolved. The FONSI and the revised EA are simultaneously being filed with the Environmental Protection Agency (EPA), State and areawide clearinghouses for review. The comment period is 30 days.

In the Federal Register of April 6, 1987 (52 FR 10887), FDA published a food additive regulation amending 21 CFR 573.920, permitting an increase in the level of selenium in complete feeds for cattle, sheep, chickens, swine, turkey, and ducks, and also in feed supplements for limit feeding and free choice salt-mineral mixtures for beef cattle and sheep. The permitted level of supplemental selenium that may be provided was increased from 0.1 ppm to 0.3 ppm in complete feed and from 1 mg/head/day to 3 mg/head/day in supplemental feeds for beef cattle. The regulation amending 21 CFR 573.920 was issued in response to a food additive petition filed by the American Feed Ingredients Association (AFIA). The AFIA petition was supported by an EA and CVM prepared a FONSI for the action. (Both of these documents are included as attachments to the Schering revised EA, which follows.)

Objections were received to the April 1987 food additive regulation, including: objections relating to the potential environmental impact of the increased use of selenium as a nutritional supplement in domesticated animals. CVM is still reviewing these comments and the associated scientific literature. The Schering bolus may be affected by any future agency decision taken to resolve the environmental or other objections to

the regulation, 21 CFR 573.920, as amended in April 1987, that permits the current level of selenium supplementation for animals.

The Schering food additive petition contains a revised EA that is adequate to determine that the new dosage form will be manufactured in a manner that is safe for the environment. Additionally, the firm has provided some mitigations to reduce the potential for adverse environmental impact due to use of the product. The product is labeled to warn against the use of the bolus in areas where animals already receive sufficient selenium or where selenotoxic plants occur (these are areas where there is already sufficient selenium in forage and locally grown feeds due to adequate or excess quantities of selenium in the soil). The bolus also must not be used in conjunction with any other form of selenium supplementation. Finally, the firm has provided instructions for the return of damaged or out-of-date products to the manufacturer for proper disposal.

Therefore, the Center for Veterinary Medicine has tentatively determined that it will not be necessary to prepare an environmental impact statement for this individual food additive petition.

1/27/89
Date

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1/27/89
Date

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Attachment:
Schering's May 6, 1988 EA with Appendices